EUROPEAN
COMMISSION

Brussels, 17.8.2022
C(2022) 6055 final

COMMISSION IMPLEMENTING DECISION

of 17.8.2022

amending the marketing authorisation granted by Decision C(2018)5718(final) for "Yescarta - axicabtagene ciloleucel", an orphan medicinal product for human use following an assessment of a periodic safety update report under Article 28 of Regulation (EC) No 726/2004

(Text with EEA relevance)

(ONLY THE DUTCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1], and in particular Article 10 and 28 thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 23 June 2022 by the Committee for Medicinal Products for Human Use on the periodic safety update report for this medicinal product,

Whereas:

(1) The placing on the market of the medicinal product "Yescarta - axicabtagene ciloleucel" was authorised by Commission Decision C(2018)5718(final) of 23 August 2018.

(2) The marketing authorisation holder submitted a periodic safety update report for this medicinal product. This report was assessed by the Pharmacovigilance Risk Assessment Committee as to whether the marketing authorisation concerned should be maintained, varied, suspended or withdrawn.

(3) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex IV to this Decision, shows that a decision should be taken amending the marketing authorisation for the medicinal product concerned.

(4) Decision C(2018)5718(final) should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(5) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2018)5718(final) should therefore be replaced.

[1] OJ L 136, 30.4.2004, p. 1.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2018)5718(final) is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Kite Pharma EU B.V., Tufsteen 1, 2132 NT Hoofddorp, Nederland.

Done at Brussels, 17.8.2022

For the Commission

Sandra GALLINA
Director-General